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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,664	06/26/2003	Takatomo Hisamatsu	018961-063	3993

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EXAMINER	
RYCKMAN, MELISSA K	
ART UNIT	PAPER NUMBER
3773	

MAIL DATE	DELIVERY MODE
06/19/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/603,664	HISAMATSU ET AL.	
	Examiner	Art Unit	
	MELISSA RYCKMAN	3773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 January 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-11,25 and 29* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-11,25 and 29* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 1/27/09 has been entered.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 2, 3, 6, 7, 11, 27, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wijeratne et al. (US 6.036670) in view of Berg et al. (US 5911715).

Wijeratne teaches a catheter comprising the following:

- a proximal shaft (32)
- an intermediate member (distal end of 32, Fig. 2) connected to a front side of said proximal shaft (where 23 passes through 32 and 22 in Fig. 2)
- a distal shaft (22) connected to a front portion of said intermediate shaft (where 38 touches 37 in Fig. 2)

- a hub (34) provided to a rear side of said proximal shaft
- a balloon (21) provided at a front portion of said distal shaft
- an inner tube shaft (23) coaxially extends through said distal shaft and said balloon and connected at a distal end of said balloon (fig. 1)
- a balloon lumen for communicating said hub to the inside of said balloon
- a guide wire lumen (23) for allowing a guide wire to be inserted through said guide wire lumen, said guide wire lumen including a distal side aperture (25) positioned on the distal side from a front end of said balloon and a proximal side aperture (26) formed in a side surface of said intermediate member (Figs. 2 and 5, the side surface of the intermediate member forms the aperture).

Wijeratne fails to teach a grooved portion as described in the claims, however Berg teaches a guide catheter capable of carrying a balloon wherein, at least a front portion, of said distal shaft (56) is configured as a grooved portion having a groove (61), said grooved portion is provided adjacent to said balloon (Fig. 9) and extends towards a proximal side of said distal shaft (Fig. 10), wherein said groove is formed into spiral shape or annular shape (fig. 10), wherein the pitch of said spiral or annular groove is changed in the direction toward the distal end of said catheter (Column 9, proximate lines 52-55), wherein the depth of said groove is changed in the direction toward the distal end of said catheter (Column 9, proximate lines 52-55), wherein said grooved portion includes a first region, a second region, and a third region disposed in this order from the distal side, and the depth of said groove in said second region is larger than

that of said groove in said third region and the depth of said groove in said first region is larger than that of said groove in said second region (fig. 11 c) and wherein said groove is formed in an outer surface of said distal shaft (fig. 9) in order to provide a device having increased flexibility for better maneuverability. Berg teaches said groove possessing a depth which chanqes relative to a longitudinal extent of the distal shaft (Fig. 11) so as to be relatively larger on a distal side of said grooved portion and relatively smaller on a proximal side of said grooved portion.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Wijeratne with the grooved portion as taught by Berg in order to provide a device having increased flexibility for better maneuverability.

Claims 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wijeratne et al. (US 6.036670) and Berg (US 5911715), as applied to claim 1 above, and further in view of Keith (US 5217482).

Wijeratne and Berg teach the claimed invention, but are silent regarding the hardness of the distal shaft, however Keith teaches a catheter comprising the following:

- wherein said distal shaft is made from a polymer material having a Shore D hardness of 70 or more and a flexural modulus of 11,000 kgf/cmz or more (Column 7, proximate lines 34-36). Keith teaches wherein the distal shaft is formed of a high-density polyethylene, which inherently has a Shore D hardness of 70 or more and a flexural modulus of 11,000 kgf/cm2.

- wherein said distal shaft has a distal portion (34) and a proximal portion (110), and the rigidity of said proximal portion (110) of said distal shaft is lower than that of said proximal shaft (22) and is higher than that of said distal portion (34) of said distal shaft (Column 9, proximate lines 1-10).

It would have been obvious to one of ordinary skill in the art to use the material of Keith the invention of Wijeratne and Berg, as HDPE (high density polyethylene) is a commonly used material in the art, and has been proven successful.

Claims 4, 9, and 25 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Wijeratne and Berg, as applied to claim 1, and further in view of Keith and as a matter of design choice.

The combination of Wijeratne, Berg and Keith teach all of the limitations of preceding dependent claims 1 and 12 as previously disclosed, but fails to describe the following:

- wherein the depth of said groove is in a range of 30 to 90% of the wall thickness of said distal shaft.
- wherein the product of an outer diameter (S) of said distal shaft of said grooved portion and a flexural modulus (E) of a material forming said distal shaft is in a range of 500 kgf/cm or more.

Regarding the limitations wherein the groove is in a range of 30 to 90% of the wall thickness of said distal shaft and the product of an outer diameter (S) of said distal shaft of said grooved portion and a flexural modulus (E) of a material forming said distal shaft

is in a range of 500 kgf/cm or more, the combination of Wijeratne, Berg and Keith teach a device wherein the grooves are in place in order to provide a smooth transition from the proximal rigid portion to the more flexible distal portion (Berg), but does not teach the exact depth of the grooves in relation the thickness of the shaft. It appears that the combination of Wijeratne, Berg and Keith performs the task of providing a smooth transition from the proximal rigid portion to the more flexible distal portion equally well as that disclosed in the application. Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to disclose make the depth of the groove in a range of 30 to 90% of.the wall thickness of the distal shaft and the product of an outer diameter (S) of said distal shaft of said grooved portion and a flexural modulus (E) of a material forming said distal shaft is in a range of 500 kgf/cm or more since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233.

Response to Arguments

Applicant's arguments filed 2/27/09 have been fully considered but they are not persuasive. The applicant generally argues the following:

- Berg does not teach transition zone 61 is at the portion adjacent to the balloon

- It would not have been obvious to modify Wijeratne's outer body tube to include a front portion configured as a grooved portion having a groove and positioned on a rear side of the balloon.

The examiner respectfully disagrees with the applicant. Berg teaches element 61 adjacent to a balloon. With the broadest reasonable interpretation to the term "adjacent", means "lying near or close". Element 61 of Berg is adjacent to the balloon as seen in Fig. 9. The examiner's position is it would have been obvious to one of ordinary skill in the art to modify Wijeratne's outer body tube as Berg teaches that flexibility is necessary (col. 2, ll. 34-46), and the positioning of the grooved portion on the proximal side of the balloon is shown in Wijeratne (Fig. 9).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MELISSA RYCKMAN whose telephone number is (571)272-9969. The examiner can normally be reached on Monday thru Friday 7:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jackie Ho can be reached on (571)-272-4696. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MKR
/Melissa Ryckman/
Examiner, Art Unit 3773

/(Jackie) Tan-Uyen T. Ho/
Supervisory Patent Examiner, Art Unit 3773